

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Michael Kerin McNAMARA

Title: IMMUNOGENIC LHRH COMPOSITIONS AND METHODS RELATED THERETO

Appl. No.: 09/462,089

Filing Date: 05/01/2000

Examiner: Ewoldt, G.R.

Art Unit: 1644

**RECEIVED****JUL 12 2001****TECH CENTER 1600/2900****RESPONSE TO RESTRICTION REQUIREMENT**

Commissioner for Patents  
 Box NON-FEE AMENDMENT  
 Washington, D.C. 20231

Sir:

In response to the restriction requirement set forth in the Office Action mailed April 9, 2001, Applicant hereby provisionally elects Group I, Claims 1-8 for examination. This election of claims is made with traverse and without prejudice to Applicant's right to pursue the non-elected claims in one or more divisional applications in due course. The deadline for response to this office action has been extended for two months, to July 9, 2001, by filing a Petition for Extension of Time and payment of the appropriate fee under 37 C.F.R. §§ 1.136 and 1.17(a)(2).

The Commissioner may require restriction if two or more independent and distinct inventions are claimed in one application (35 U.S.C. § 121). In the present case, although the claimed subject matter may be classified into different classes, the inventions are not independent.

The Examiner has asserted that more than one invention exists in the current application and has required restriction under 37 C.F.R. § 1.499. The Examiner has required restriction between Claims 1-8 (Group I), drawn to a composition comprising an LHRH:diphtheria conjugate and an ionic polysaccharide; Claim 9 (Group II), drawn to a method of eliciting an immune response to LHRH; Claims 10-11, 13-17, and 20-21 (Group

III), drawn to a method of inhibiting reproductive capacity in a male animal; Claims 10, 12-15, 18-19, and 22-23, (Group IV), drawn to a method of inhibiting reproductive capacity in a female animal; Claims 24-29 (Group V), drawn to a method of achieving production gains in livestock; Claims 30-34 (Group VI), drawn to a method of inhibiting the growth of cells; Claims 35-36 (Group VII), drawn to a method of downregulating libido.

In making the assertion that more than one invention exists, the Examiner relies on PCT Rule 13.1 in applying the "unity of invention" standard. In view of PCT Rule 13.1, Applicant respectfully disagrees with the Examiner that more than one invention exists in the current application, and asserts that all of the claims in the current invention share the same special technical feature as outlined in PCT Rule 13.1.

Indeed, the PCT Administrative Instruction, Annex B, Part 2, Example 1 states:

Claim 1: A method of manufacturing chemical substance X.

Claim 2: Substance X.

Claim 3: The use of substance X as in an insecticide.

Unity exists between Claims 1, 2 and 3. The special technical feature *common to all claims* is X." (Emphasis added).

Thus, according to the PCT, claims possess unity if the special technical feature is common to all claims. Further, the PCT Administrative Instructions (Annex B, Part I, (c)(i)) state that "If the independent claims avoid the prior art and satisfy the requirement of unity of invention, *no problem of lack of unity arises in respect of any claims that depend on the independent claims*. In particular, *it does not matter if a dependent claim itself contains a further invention*. (emphasis added).

Thus, if all independent claims of the current invention avoid the prior art, then all claims dependent upon these independent claims will possess unity of invention and must be examined in concert. In the current context, all dependent claims of the current application have in common the feature of a composition comprising a LHRH-diphtheria conjugate and an ionic polysaccharide, which is a special technical feature, among several,

of the present invention that unify all the claims of the current application. Accordingly, all claims of the current application should be examined together.

In support of this contention that the invention lacks unity, the Examiner cites U.S. Patent No. 5,378,688 (hereinafter "the 688 patent") and U.S. Patent No. 5,403,586 (hereinafter "the '586 patent") and asserts that the combination of these two patents renders the composition of the current invention obvious and thus not involving a special technical feature. Applicant respectfully disagrees with this assertion. To establish a case of *prima facia* obviousness, the Examiner must show, among other criteria, that the references upon which she or he relied teach all the limitations of the currently claimed invention. *In re Royka* 490 F.2d 981, 985 (C.C.P.A. 1974). The '688 patent does not teach a composition comprising an LHRH-diphtheria conjugate and an ionic polysaccharide, and the '586 patent does not cure this deficiency.

Furthermore, even if every element of the currently claimed invention was taught by the combination of the '688 patent and the '586 patents, which applicants do not concede, these circumstances would not have rendered the invention obvious, since there must be "some teaching, suggestion, or motivation to combine the references." *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998). See *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988) (what is needed is a reason, suggestion, or motivation in the prior art that would motivate one of ordinary skill to combine the cited references, and that would also suggest a reasonable likelihood of success in making or using the claimed invention as a result of that combination).

The Examiner also states that the claims must be restricted in accordance with 37 C.F.R. 1.499, which also relies on the unity of invention standard as outlined in PCT Rule 13.1. Without acquiescing to the Examiner's characterizations of the claims of the current application, Applicant respectfully disagrees with the Examiner's contention that Applicant must "elect a single invention." (PTO Prosecution File Wrapper Paper No. 9, page 2). This election of a single invention is simply incorrect under the "unity of invention" standard that the Examiner has used in requesting restriction. Indeed, 37 C.F.R. § 1.475(b) states, in relevant part, that "An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims

are drawn only to one of the following combinations of categories: ... (2) A product and process of use of said product ...." Thus, under the rule that the Examiner has cited in support of the restriction, the product *and* method of use "will be considered to have unity of invention" (37 C.F.R. 1.475(b)) (emphasis added). Accordingly, Applicant asserts that he is entitled to have (1) the product and (2) the process of use claims examined simultaneously.

Finally, it is considered that the claims of the Examiner's Groups II to VII are linked to the claims of the Examiner's Group I, to comprise a single inventive concept, which is the induction of an immune response to an LHRH by use of the composition as recited in any one of claims 1-8. In other words, it is considered that there is a single inventive concept in the novel composition designed to elicit an immune response to LHRH and methods of using this composition so as to lead to the claimed biological outcomes.

In conclusion, Applicant asserts that the claims of the current invention relate to a single inventive concept. In addition, all the claims share a special technical feature that is not obvious in view of any references, whether or not they were cited by the Examiner. In view of the foregoing arguments, Applicant respectfully requests that the Examiner withdraw the present requirement that certain claims of the current application be restricted from other claims during examination.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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